General

Guideline Title

Society of Interventional Radiology position statement on injection safety: improper use of single-dose/single-use vials.

Bibliographic Source(s)

Silberzweig JE, Khorsandi AS, Dixon RG, Gross K, Nikolic B. Society of Interventional Radiology position statement on injection safety: improper use of single-dose/single-use vials. J Vasc Interv Radiol. 2013 Jan;24(1):111-2. [12 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

An essential feature of injection practice involves the safe administration of a medication packaged in a single-dose vial (SDV) or single-use vial. The Centers for Disease Control and Prevention (CDC) note that improper use of a medication packaged in an SDV can place a patient at increased risk for acquiring a health care–related infection. Medication from an SDV is intended for parenteral administration for a single patient during a single procedure. SDVs are labeled as such in the manufacturer's package insert. The CDC states that SDVs must not be used for multiple patients. Even if an SDV contains more medication than is needed for a single patient, that vial should not be used for more than one patient nor stored for future use in the same patient.

In contrast with an SDV, a multidose vial (MDV) of a medication contains more than a single medication dose. MDVs are labeled as such by the manufacturer and typically contain an antimicrobial preservative agent to help prevent bacterial growth. The preservative agent has no effect on viruses and does not protect against contamination when health care personnel fail to follow safe injection practices. MDVs are discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. An MDV used for more than one patient is required to be kept in a centralized medication area and not accessed in the immediate patient treatment area (e.g., procedure room, patient room). If MDVs enter the treatment area, they should be dedicated for single-patient use and discarded immediately after use.

A medication in an SDV can become contaminated and act as an infection source if administered to multiple patients. The infection outbreak risk is particularly increased with repeated SDV access with more than one needle whenever an SDV is used for more than one patient. Since the CDC safe injection guidelines were published in 2007, the CDC has reported 21 outbreaks associated with SDV medications administered for multiple patients: seven outbreaks involved infections transmitted through contamination by blood, and 14 involved bacterial infections. Two recently reported outbreaks of invasive *Staphylococcus aureus* infection were confirmed in 10 patients being treated for pain in outpatient clinics in Delaware and Arizona, in which SDVs were reused for multiple patients. Transmission of life-threatening but preventable bacterial infections by failing to follow safe-injection recommendations can result in an infection outbreak that causes unnecessary morbidity and draws attention of the

media and regulatory agencies.

Concerns have been raised about whether these guidelines and related policies contribute to drug shortages and increased medical costs to health care providers. On May 2, 2012, the CDC restated its 2007 position regarding the use of SDVs in response to "inaccuracies" being disseminated to health care providers. The CDC recognized the problem of drug shortages; however, such shortages are noted to be the result of manufacturing, shipping, and other issues unrelated to the guidelines. The CDC noted that lowering safety standards will not address the problem of drug shortages.

Under certain conditions, however, such as during limited drug availability, it is permissible for health care facilities to repackage SDVs into smaller doses, each intended for a single patient use. Repackaging is allowable if performed by qualified health care personnel under specific conditions according to standards in United States Pharmacopeia (USP) General Chapter 797, Pharmaceutical Compounding–Sterile Preparations, as well as the manufacturer's recommendations pertaining to safe storage of that medication outside of its original container. On June 15, 2012, the Centers for Medicare and Medicaid Services (CMS) issued a memorandum that stated that health care providers that do not comply with USP standards for SDVs may be cited for deficiencies under applicable federal infection control standards.

SDVs must never be used for multiple patients unless specific conditions allow repackaging by qualified health care personnel under USP standards. It is the responsibility of interventional radiologists and other licensed personnel to adhere to best care practices for the safe performance of minimally invasive treatments.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Infections due to improper use of single-dose/single-use vials

Guideline Category

Prevention

Clinical Specialty

Internal Medicine

Preventive Medicine

Radiology

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Pharmacists

Physician Assistants

Physicians

Guideline Objective(s)

To provide guidelines for prevention of improper use of single-dose or single-use vials

Target Population

Patients receiving injections of a medication packaged in single-dose or single-use vials

Interventions and Practices Considered

Use of safe injection practices for single-dose or single-use vials of medications

Major Outcomes Considered

Infection outbreak risk

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

An in-depth literature search was performed using electronic medical literature databases, including the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and Medline databases. No inclusion/exclusion criteria were applied. The literature search was conducted from 1995 to 2012. Search terms used were *injection, infection,* and *safe use of single-dose/single-use vial*.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Safe administration of a medication packaged in a single-dose vial (SDV) or single-use vial

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

A primary goal of the Society of Interventional Radiology (SIR) is ensuring high-quality outcomes and patient safety in vascular and interventional radiology. The clinical practice guidelines of the SIR attempt to define practice principles that generally should assist in producing high quality

medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Jan

Guideline Developer(s)

Society of Interventional Radiology - Medical Specialty Society

Source(s) of Funding

Society of Interventional Radiology

Guideline Committee

Society of Interventional Radiology Safety and Health Committee

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

None of the authors have identified a conflict of interest.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Society of Interventional Radiology Web site

Print copies: Available from the Society of Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

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